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| 10/527,628      | 05/25/2005  | Prasad Koteswara Kapa | PI/4-32685A         | 9537             |

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NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 104/3  
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| EXAMINER |
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RODRIGUEZ-GARCIA, VALERIE

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| ART UNIT | PAPER NUMBER |
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4161

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09/19/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                             |                                    |  |
|------------------------------|---------------------------------------------|------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/527,628        | <b>Applicant(s)</b><br>KAPA ET AL. |  |
|                              | <b>Examiner</b><br>VALERIE RODRIGUEZ-GARCIA | <b>Art Unit</b><br>4161            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.                                                |

### **DETAILED ACTION**

This application is a 371 of PCT/EP03/10416 filed on 09/18/2003.

#### ***Election/Restrictions***

1) Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-9, drawn to a process for preparing a compound of formula (VIII) where  $X = CH_2$ ,  $n = 1$  and  $R_2$ ,  $R_3$ ,  $R_4$  and  $R_5$  are independently hydrogen or aliphatic. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group II, claims 1-3 and 5-9, drawn to a process for preparing a compound of formula (VIII) where  $X$ ,  $n$  and  $R_2$ ,  $R_3$ ,  $R_4$  and  $R_5$  collectively are not those of Group I. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group III, claims 10-12 and 15-16, drawn to a process to form a compound of formula (III) where  $R_2$ ,  $R_3$ ,  $R_4$  and  $R_5$  are independently hydrogen or alkyl. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group IV, claims 10, 12 and 16 drawn to a process to form a compound of formula (III) where  $R_2$  and  $R_3$  and/or  $R_4$  and  $R_5$  collectively form a  $C_{4-7}$  cycloalkyl. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group V, claims 13-14, drawn to a process to form a compound of formula (IV) where  $R_2$ ,  $R_3$ ,  $R_4$  and  $R_5$  are independently hydrogen or alkyl. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group VI, claim 13, drawn to a process to form a compound of formula (IV) where  $R_2$  and  $R_3$  and/or  $R_4$  and  $R_5$  collectively form a  $C_{4-7}$  cycloalkyl. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group VII, claims 17-20, drawn to a process to form a compound of formula (V) where  $R_2$ ,  $R_3$ ,  $R_4$  and  $R_5$  are independently hydrogen or alkyl. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group VIII, claim 17, drawn to a process to form a compound of formula (V) where  $R_2$  and  $R_3$  and/or  $R_4$  and  $R_5$  collectively form a  $C_{4-7}$  cycloalkyl. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group IX, claims 21-25, drawn to a process to form a compound of formula (VII) where  $X = CH_2$ ,  $n = 1$  and  $R_2$ ,  $R_3$ ,  $R_4$  and  $R_5$  are independently hydrogen or alkyl. If this

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group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group X, claims 21 and 24-25, drawn to a process to form a compound of formula (VII) where  $X = CH_2$ ,  $n = 1$ ,  $R_2$  and  $R_3$  and/or  $R_4$  and  $R_5$  collectively form a  $C_{4-7}$  cycloalkyl. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group XI, claims 21-25, drawn to a process to form a compound of formula (VII) where  $X$ ,  $n$  and  $R_2$ ,  $R_3$ ,  $R_4$  and  $R_5$  collectively are not those of Groups X or XI. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group XII, claims 26-29, drawn to a process to form a compound of formula (VIII) where  $X = CH_2$ ,  $n = 1$  and  $R_2$ ,  $R_3$ ,  $R_4$  and  $R_5$  are independently hydrogen or alkyl. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group XIII, claims 26-29, drawn to a process form a compound of formula (VIII) where  $X$ ,  $n$  and  $R_2$ ,  $R_3$ ,  $R_4$  and  $R_5$  collectively are not those of Groups XIII. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group XIV, claims 30-34, drawn to a compound of formula (I) where  $R_2$ ,  $R_3$ ,  $R_4$  and  $R_5$  are independently hydrogen or alkyl. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

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Group XV, claims 30-32, drawn to a compound of formula (I) where  $R_2$  and  $R_3$  collectively form a  $C_{4-7}$  cycloalkyl. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group XVI, claims 35-37, drawn to a compound of formula (VII) where  $X = CH_2$ ,  $n = 1$  and  $R_2$ ,  $R_3$ ,  $R_4$  and  $R_5$  are independently hydrogen or alkyl. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

Group XVII, claims 35-37, drawn to a compound of formula (VII) where  $X$ ,  $n$  and  $R_2$ ,  $R_3$ ,  $R_4$  and  $R_5$  collectively are not those of Groups XVII. If this group is elected, a further election of a single disclosed species is also required. Further restriction based on the election may be made.

The inventions listed as Groups I-XVIII do not relate to a single general inventive concept under 35 USC 121 or PCT Rule 13.1 because they lack the same or corresponding special technical features:

In the instant case, the special technical feature of Groups I–IV and XIV-XV is the component of formula (I). The component of formula (I) of these groups does not present a contribution over the prior art because at least one Markush alternative (p. 1257, Table I, entry 1) has been previously disclosed in *J. Org. Chem.* **1972**; 37(8): p.1256 (cited in the international search report). As such, Group I does not share a special technical feature with Groups II-XVII. Therefore, the claims are not so linked within the meaning of PCT Rule 13.2 so as to form a single inventive concept, and unity

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between Groups I -XVII and between Markush species is broken. In addition the variables X and n of Groups I-II, IX-XIII and XVI-XVII result in so many permutations that no common core can be constructed thus the lack of a special technical feature is apparent.

### **Election of Species**

2) This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- Process' conditions (claims 12 and 16)
- Drawing of the exact chemical structures (no variables) of the compounds or components of Formulae I through XIII (contained on the elected group)

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Regardless of the Group selected, applicant is required to define an exact compound or component of formulae (I-XIII) with an exact chemical structure, no variables, from all the possible structures recited in the generic claims 1-11, 15 and 17-35. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

a) Each chemical species is a distinct chemical lacking a special technical feature in view of the fact that one of the chemical species is not novel and has been previously disclosed in the prior art (*J. Org. Chem.* **1972**; 37(8): p.1256 and cited in the international search report).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is *presented prior to* final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.



In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be **allowable**, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*; *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include all the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Filing of appropriate terminal disclaimer in anticipation of a rejoinder may speed prosecution and the process of rejoinder.

- 3) Applicant is advised that the reply to this requirement to be complete must include (i)  
an election of a species or invention to be examined even though the requirement be

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traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

- 4) The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE RODRIGUEZ-GARCIA whose telephone

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number is (571)270-5865. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VRG

/Patrick J. Nolan/  
Supervisory Patent Examiner, Art Unit 4161